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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/643,673
Filing Date: August 19, 2003
Appellant(s): HYON ET AL.

David L. Suter
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10-26-2009 appealing from the Office action mailed 12-22-2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

US Application Serial No. 11/643,674.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,030,402	ZACHARIADES	07-1991
3,886,056	KITAMARU et al	05-1975

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection under 35 U.S.C. 251

Claims 104, 109-111, 139, 149-153 and 164-168 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

The following subject matter appears to be an attempt to recapture subject matter surrendered during prosecution of the parent application: The amendments cited below were made during prosecution in parent application Serial No. 08/640,738, which issued as Patent 6,168,626.

The recitation “article” in claims 104 and 139 is broader than the recitation of a “molded article” set forth in the original claims. In Amendment B, filed 04-02-1997, the phrase “molded article” was amended to set forth a **“molded article having orientation of crystal planes”** in order to distinguish over Rosenzweig, US 5,030,487. The present term “article” is broader in scope than the phrase “molded article” or the phrase “molded article having orientation of crystal planes”. The phrase “molded article having orientation of crystal planes” was further amended to read “molded article having orientation of crystal planes **in a direction parallel to a compression plane**” in the Amendment C, filed 12/5/1997, in order to distinguish over cited Patent 4,655,769 to Zachariades. The present term UHMWPE “article” is a broadening of the amended claim language wherein “molded article” was changed to read **“molded block”** in Amendment F filed 02-25-1999 in order to distinguish over Patent 3,886,056 to Kitamaru et al. In summary, the method claims in the parent application were limited to read an UHMWPE **“molded block having orientation of crystal planes in a direction parallel to a compression plane”** in order to distinguish over the prior art cited during prosecution.

With respect to step (a) in the instantly claimed method, the instant claims are broadened by failing to recite the limitation **“having a molecular weight not less than 5 million”** to define the UHMWPE article in the step of slightly crosslinking an UHMWPE article by irradiating the article with a high energy ray. Applicant added the limitation **“having a molecular weight not less than 5 million”** to define the UHMWPE molded block in the step of slightly crosslinking an UHMWPE molded block by irradiating the block with a high energy ray in the parent application. This limitation was added in Amendment H filed 05-04-2000 in order to distinguish over Kitamaru et al ‘056.

With respect to step (c) in the instantly claimed method, the instant claims are broadened by failing to recite that the article is made by compression deforming the heated article **“by compressing the block in a direction perpendicular to a compression plane so as to deform the block”**. This limitation was added in Amendment D filed 09-03-1998 in order to resolve the rejection under 35 US 112, second paragraph, that the phrase “orientation of crystal planes in a direction parallel to a compression plane” discussed above was indefinite when the orientation of the compression plane was not defined.

With respect to step (d) in the instantly claimed method, the instant claims are broadened by failing to recite the limitation **“said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane”**. Amendment G filed 09-10-1999 introduced this limitation to distinguish the “molded block” recitation from the films and sheets disclosed by Kitamura et al.

With respect to step (d), in the instantly claimed method, the instant claims are broadened by failing to recite the limitation **“under pressure”** in the phrase “cooling the article while maintaining the deformed state” instead of “keeping the block in a deformed state under pressure”. Amendment G filed 09-10-1999 also introduced the limitation **“under pressure”** to the phrase “keeping the block in a deformed state under pressure” in order to distinguish over the process taught by Kitamura et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 104, 109-111, 139, 149-153 and 164-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zachariades (5,030,402) in view of Kitamaru et al (3,886,056). Zachariades teaches compression deformation of oriented UHMWPE to obtain enhanced properties. Compression molding at temperatures between 80°C and the melting temperature of the polymer, preferably between 100°C and 130°C, and shaping into a final product are taught in column 3, lines 25-44. Zachariades also teaches maintaining pressure during and after cooling to ambient temperature to aid in retaining the attained chain orientation (column 4, lines 1-11). Zachariades further teaches that the molded UHMWPE can be thermally annealed after removal from the mold (column 6, lines 50-54). The difference from the instantly claimed method is that Zachariades treats unirradiated polyethylene and discloses radiation crosslinking only as a post-processing step (column 4, lines 11-18).

Kitamaru et al disclose a process for irradiating polyethylene, including polyethylene preferably having a molecular weight from 2×10^5 to 1×10^6 and 4×10^6 , with low dose ionizing radiation to produce crosslinked polyethylene having a gel content of at least one weight percent (column 1, line 65, to column 2, line 50, and column 3, lines 1-11). A process comprising heating to a molten state, extending the polyethylene under increased pressure, and cooling the article while the extended dimension is maintained is taught in column 3, lines 13- 45. Irradiation followed by compression at 180°C, followed by cooling and orientation of crystal planes in a

direction parallel to the compression plane is disclosed in Examples 1-3. With respect to claims 150 and 152, polyethylene having a molecular weight 4×10^6 and dosages from 0.2 to 16 Mrads are taught in column 3, lines 1-10.

It would have been obvious to one skilled in the art at the time of the invention to irradiate UHMWPE, as taught by Kitamaru et al in an analogous method, to provide a slightly crosslinked UHMWPE preform as the starting UHMWPE to be used in the compression molding method steps for orienting and extending UHMWPE taught by Zachariades. With respect to claims 110-111 and 139, it would have been obvious to one skilled in the art at the time of the invention to determine the optimum temperature and time period for thermally annealing the UHMWPE after removal from the mold, from the disclosure of Zachariades. With respect to claim 151, the product produced by the process taught by Kitamaru et al would be expected to include an irradiation product having 0.1 to 10 crosslinking points per 1 molecular chain because low dose irradiation is employed to achieve a low gel content. Zachariades teaches that those skilled in the art to which the disclosed invention relates would recognize changes and different embodiments possible without departing from the spirit and scope of the invention. Kitamaru et al provide motivation to employ irradiated UHMWPE by teaching that irradiation crosslinked UHMWPE can be deformed under pressure and will provide a high melting temperature and softening temperature polyethylene with improved transparency and excellent dimensional stability at high temperatures (column 1, lines 5-9, and column 2, lines 13-25). One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of obtaining both enhanced properties taught by Zachariades resulting from the

disclosed compression deformation method and enhanced properties taught by Kitamaru et al resulting from irradiation crosslinking before deformation of the crosslinked UHMWPE.

(10) Response to Argument

35 USC 251 Rejection:

Appellant argues that the instant claims, although broadened in some aspects, are more narrow in significant aspects than the claims of the parent claims issued in US 6,168,626 and thus avoid recapture of subject matter surrendered during prosecution of the '626 Patent.

Appellant appears to rely on the decision in *Mentor Corp. v. Coloplast Inc.*, 998 F.2d 992,996,27 U.S.P.Q. 2d 1521,1525 (Fed. Circ. 1993) and the statement that "Reissue claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule.".

Appellant further relies upon analysis of recapture by a three-step process as summarized in *Pannu v. Storz Instruments, Inc.*, 258 F.3d 1366, 59 U.S.P.Q. 2d 1587 (Fed. Cir. 2001). The broadened aspects of the instant claims and their relation to surrendered subject matter are set forth herein above in the rejection under 35 USC 251. Appellant argues that the narrower aspects of the instant claims are more significant than the broadened aspects and avoid the recapture of the broadened aspects in the instant claims. See *Mentor Corp. v. Coloplast Inc.*

Pannu Analysis Step 2: Appellant argues that the claims are not barred by the recapture rule because the broader aspects of the reissued claims do not relate to subject matter surrendered during prosecution of the '626 Patent because the present claims are directed to a different invention than prosecuted in the issued parent. Appellant further argues that appellant's remarks

and amendments in pursuit of the original claims are not relevant to the scope of the instant claims because the instant claims were restricted from the original claims as being drawn to a distinct and independent invention. These arguments are unpersuasive because issued claims 3-6 in US 6,168,626 are drawn to a method encompassing the method set forth in the instant claims. The claims prosecuted in US '626 were not restricted with respect to method, intermediate product and final product and, thus, had to be considered as Group I in the restriction of claims filed in reissue application 10/141,374. Appellant points to claims 229 (Group VIII) and 264 (Group X) in 10/141,374 as leading to current claims 104 and 139. See Table 2 on pages 14-15 of the Appeal Brief. The Group VIII and Group X claims in 10/141,374 were restricted on the basis of significant differences in the recited method steps that would have been expected to produce products having significantly different properties. However, it is noted that current claims 104 and 139 include significant limitations, such as the compression deformation step and cooling while maintaining the deformed state recited in the claims of US '626, compared with original claims 229 and 264. The different issue remaining in the instant claims is the limitation of heating to a compression deformation temperature between 50⁰ C below the melting point and the melting point of the crosslinked UHMWPE. This issue, although narrower, is included in the recitation "heating the crosslinked ultra high molecular weight polyethylene molded block up to a compression deformation temperature" and "compression-deforming the block" in claim 3 of US '626. Thus the instant claims under appeal are not considered to present an issue unrelated to the original patented claims and the prosecution thereof. It is the instant claims under appeal that are to be considered rather than the claims originally presented in the original reissue application 10/141,374.

Appellant further argues that, if the present claims are viewed as being the same invention as those issued, they are materially narrowed in other aspects so as to avoid recapture. Applicant argues that the present amendment narrowing the recited heating to heating between a temperature 50°C below the melting point and the melting point instead of heating from a temperature 50°C below the melting point to 80°C above the melting point of the UHMWPE avoids the recapture bar. It is noted that claim 3 of US '626 recites heating to a compression-deformable temperature of the crosslinked UHMWPE and that it is dependent claim 5 that recites heating from a temperature 50°C below the melting point to 80°C above the melting point of the crosslinked UHMWPE.

These arguments are unpersuasive for the following reasons. In the instant case, reissue claim 104 is considered to be as broadened in an aspect germane to surrendered subject matter in response to a prior art rejection and narrowed in another aspect completely unrelated to the rejection of claims in the issued parent and thus barred by the recapture rule. Claim 104 is broader by recitation of "UHMWPE article" rather than UHMWPE "molded block...compression plane", "compression deforming the heated article" instead of "compression-deforming...deform the block", and omitting the requirement of a given "thickness range" after cooling. Claim 104 is narrowed by recitation of "low dose irradiation" and "heating...to compression deformable temperature between 50°C below the melting point of said article and said melting point". The narrowing of the irradiation dose and the compression deformable temperature recitation is not considered to be directed to an amendment and/or argument made to overcome a prior art rejection in the original prosecution and thus there is recapture of surrendered material. See MPEP 1412.02 [R-5], part C. The Third Step, section 2(a).

Issued claim 3 merely recites “heating...to a compression-deformable temperature” and does not mention “low dose” irradiation. The issue “heating...to a compression-deformable temperature” compared with “heating to a compression deformable temperature between 50⁰C below the melting point of said article and said melting point” is not related to the rejections set forth in the prosecution of the original application.

In *Mentor Corp. v. Coloplast Inc.*, the Court found that “the added limitations do not narrow the claims in any material respect compared with their broadening”. The decision was that the added recitation that the catheter material by “flexible” did not materially limit the scope of a claim that already recited the material was “resilient”. The facts in the instant application are similar to those in *Mentor Corp. v. Coloplast Inc.* The recitation “heating...to compression deformable temperature between 50⁰C below the melting point of said article and said melting point” in the instant claims is not considered to materially limit the scope of a claim that recites heating wherein the “compression deformable temperature is in a range of 50⁰ C. lower than a the melting temperature of the crosslinked ultra high molecular weight polyethylene to 80⁰C. higher than the melting temperature” in claim 5 of US ‘626.

In *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001) the narrowed limitations relied upon are considered to present a fact situation similar to the instant case. In *Pannu v. Storz Instruments Inc.*, the recitation that the snag resistant means be “at least three times greater” instead of “substantially greater” than the width of the haptics is a narrowed recitation similar to the recitation in the instant claims limiting the temperature range to “between 50⁰C below the melting point of said article and said melting point” instead of a “range of 50⁰ C. lower than a the melting temperature of the crosslinked ultra high molecular weight

polyethylene to 80°C. higher than the melting temperature” in the patented claim 5. The claims in *Pannu v. Storz Instruments Inc.* were found not to be narrowed in any material respect compared with their broadening”.

Appellant argues that the narrowing aspect of the instant claims is not “completely unrelated” to claim rejections made during prosecution of the ‘626 Patent. See *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997).

Appellant’s argument that the claims in the prosecution of the issued patent were patentable without Amendment B to overcome Rosenzweig ‘487 is not persuasive with respect to the narrowed aspect of the instant claims being related to a prior art rejection in the ‘626 Patent. Appellant has not pointed to a rejection wherein the compression-deformation temperature was an issue.

Appellant’s argument that the claims in the prosecution of the issued patent were patentable without Amendments F, G or H to distinguish over Kitamaru et al ‘056 is not persuasive with respect to the narrowed aspect of the instant claims being related to a prior art rejection in the ‘626 Patent. Appellant has not pointed to a rejection wherein the compression-deformation temperature was an issue. Kitamaru ‘056 discloses heating UHMWPE at temperatures above the melting point and applying pressure. Although the current limitation to temperatures below or at the melting point in the instant claims would appear to distinguish over that teaching in the reference, the compression-deformation temperature was not an issue in the rejection set forth in the prosecution of the ‘626 Patent.

Appellant’s arguments that the narrowing limitations in the instant claims are “not completely unrelated” to the rejections of claims in the prosecution of US ‘626 is considered to

be a misinterpretation of the recapture rule. No amendments were made or issues discussed with respect to the compression-deformation temperatures set forth in the instant claims during prosecution of the '626 claims. The narrowing limitations are, therefore, considered to be completely unrelated to the rejections of record in the prosecution of the '626 Patent.

Appellant's arguments with respect to the rejection of claims over Kitamura et al '056 in combination with Zachariades '402 in the current reissue application establishes that the narrowing claim limitation is related to the prosecution of the instant claims, not to the prosecution of the claims in US '626.

Rejection of claims as being obvious over Zachariades in view of Kitamaru et al:

Appellant argues that there is no reason other than impermissible hindsight to combine the teachings of Zachariades and Kitamaru et al. This argument is unpersuasive. The disclosures of Zachariades and Kitamaru et al are analogous art in that both references disclose methods for treating ultra high molecular weight polyethylene. Zachariades discloses a method comprising compression-deformation in a solid state including orienting and extending a preform in more than one direction in a mold cavity, followed by cooling under compression for maintaining the orientation and extension attained. An objective is to provide enhanced and balanced planar mechanical properties and controlled dimensional stability. Zachariades Kitamaru et al disclose irradiating polyethylene to crosslink the polyethylene, followed by extending and orienting the polyethylene in at least one direction at a temperature at least an isotropic melting point of the crosslinked polyethylene, followed by cooling. The product is a high melting temperature polyethylene with excellent dimensional stability and high transparency. Kitamura et al teach

both films and sheets. Acetabular cups, such as taught by Zachariades, are usually thin films or sheets. Example 1 discloses irradiation of polyethylene and compressing the gel sample followed by cooling to room temperature. In the rejection of record, Kitamaru et al is relied upon for teaching that irradiated polyethylene can be compression-deformed and cooled. Both references teach providing products comprising crosslinked, oriented and extended polyethylene.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Appellant argues that only certain features of the secondary reference are arbitrarily selected, specifically "crosslinking before extending" from the disclosure of Kitamaru et al. This argument is not persuasive because, in the rejection of record, Kitamaru et al is relied upon for teaching that irradiated polyethylene can be compression-deformed and cooled. This is the only modification of the teaching of Zachariades required to arrive at the instantly claimed method.

With respect to the claim 139 recitation "processing said article to make said component (an artificial joint), Zachariades teaches that the compression-deformed and cooled product is simultaneously shaped into the final product and that the UHMWPE can be used as a precursor for its machining into a final product (column 3, lines 43-44, and column 12, lines 21-26).

Art Unit: 1796

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Susan W Berman/
Primary Examiner
Art Unit 1796
12/11/2009

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